

**REMARKS**

Applicants have carefully reviewed the Final Office Action mailed on July 6, 2004. Applicants respectfully traverse all objections, rejections, and assertions made by the Examiner. Claims 1-2, 6-12, and 15-18 remain pending, claims 19-21 having been withdrawn from consideration.

In paragraph 5, Claims 1-2, 6-11, and 15-18 were rejected under 35 U.S.C. § 103 by Ju et al. (U.S. Patent No. 5,599,325) in view of Muni et al. (U.S. Patent No. 5,316,706) and Jansen (Nucleating Agents for Partly Crystalline Polymers) since these claims now contain the limitations of original claims 4-5 and 13-14 of record in the Office Action mailed February 18, 2004.

In paragraph 8, the Examiner was not persuaded by the Applicants' argument regarding the 35 U.S.C. § 103 rejection of claims 4-5 and 13-14 as applied to claims 1-2, 6-12, and 15-18. Applicants respectfully traverse this objection.

Claim 1 recites a polymeric tubular member having a lumen extending the length therein, wherein the tubular member includes a pre-formed bend along a portion of the length of the tubular member, wherein the polymeric material forming at least a portion of the pre-formed bend includes a sufficient quantity of a nucleating agent dispersed therein; and wherein the nucleating agent is selected from the group consisting of talc, silica, kaolin, molybdenum disulfide, iron sulfide, sodium phenylphosphanate, sodium p-tert-butylbenzoate, monton wax, montanic ester salts, salts of monocarboxylic acids and polycarboxylic acids, an ethylene and an acrylic ester copolymer, a fumeric acid polymer, ethylene, propylene, 1,4-hexadiene, norbornadiene, and mixtures thereof. According to the MPEP § 2143:

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

It is further stated at MPEP § 2143.01:

There are three possible sources for motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art.

The first possible source for motivation to combine references is the nature of the problem to be solved. As disclosed in the present application, the problem to be solved is crystal fracturing for curved regions in shaft assemblies that increase curve retention without affecting the flexibility within the region (page 13, lines 2-6). As stated by the Examiner in the Final Office Action: "Muni does not teach reducing "cracking" or crystalline fractures adjacent curves in a catheter without significantly affecting flexibility." Not only does Muni et al. not teach or suggest reducing crystalline fractures without affecting flexibility, Muni et al. teach away from the claimed invention by inhibiting the flexibility of the catheter. Muni et al. state: "increased stiffness" and "greater forces are required to constrain the material into a given radius of curvature" (column 3, lines 44-48). This clearly is not the nature of the problem to be solved.

The second possible source for motivation comes from the teachings of the prior art. Ju et al. disclose the use of titanium dioxide, which can be a nucleating agent. However, Ju et al. disclose titanium dioxide for a use as a radiopaque filler (column 5, line 60 through column 6, line 5). Claim 1 recites "wherein the nucleating agent is selected from the group consisting of talc, silica, kaolin, molybdenum disulfide, iron sulfide, sodium phenylphosphanate, sodium p-tert-butylbenzoate, monton wax, montanic ester salts, salts of monocarboxylic acids and polycarboxylic acids, an ethylene and an acrylic ester copolymer, a fumaric acid polymer, ethylene, propylene, 1,4-hexadiene, norbornadiene, and mixtures thereof." Titanium dioxide is not disclosed by the present invention as one of the acceptable nucleating agent. Nowhere does Ju et al. teach or suggest the use of a nucleating agent or changing the crystalline structure. Therefore, there is no motivation to combine Ju et al. with Muni et al. and Jansen.

The third possible source for motivation comes from the knowledge of persons of ordinary skill in the art. When attempting to solve the problem of crystalline fractures in the curved regions of the shaft without increasing flexibility, a person of ordinary skill in the art would not look to Muni et al. Muni et al. teach a method of making a catheter more flexible through changes in the crystalline structure. A person of ordinary skill in the art would not turn to a method of making a catheter more flexible when increased flexibility is trying to be avoided.

“The Examiner must step backward in time and into the shoes worn by the hypothetical ‘person of ordinary skill in the art’ when the invention was unknown and just before it was made.... However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.” MPEP § 2142. Without the use of hindsight, a person of ordinary skill in the art at the time the invention was created would not look to combine Muni et al., who teach a more flexible catheter, with Ju et al. to prevent a catheter from cracking in the curved region.

It is not obvious to combine Muni et al. and Jansen. As the Examiner stated in the Office Action: “Jansen provides the motivation to add nucleating agents to the polymers going through thermal treatments for crystalline structure changes of Muni, because of the economic benefits to shorter cooling times and less supercooling.” (Emphasis added.) Applicants respectfully disagree with this argument. As stated above, the three possible sources of motivation to combine references are the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art. The nature of the problem to be solved is not economic benefit or cost, but reducing the crystalline fractures. Nowhere does the present invention disclose a method to try and reduce cost or become economically beneficial. One of skill in the art would not combine Muni and Jansen for the economic benefit suggested to reduce crystalline fractures in a catheter.

According to the MPEP § 2143.01: “The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).”

Therefore, since there is no motivation to combine Ju et al., Muni et al., and Jansen through the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art, there is no *prima facie* case of obviousness. Thus, claim 1 is believed not obvious in view of Ju et al. with Muni et al. and Jansen and in condition for allowance. For the similar reasons discussed above, along with other reasons, dependent claims 2 and 6-9 are believed to be in condition for allowance.

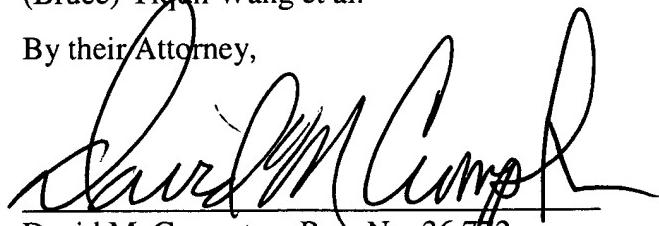
For similar reasons discussed above claim 10 and dependent claims 11 and 15-18 are also believed to be in a condition for allowance.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their Attorney,



Date: 9/3/04

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